



5th MDR Eudamed DTX ad hoc WG Meeting

Implementation plan update for DTX– Planning - Roadmap

21/03/2019

DG GROW

Content

- Meetings
- Working documents
- Implementation plan overview for 1st release
- State of play for 1st release
- Introduction webinars
- Implementation plan update

Meetings

- ~~• 29/01/2019 – Actor Registration WG~~
- ~~• 07/02/2019 – Clinical Investigations WG~~
- ~~• 21/02/2019 – NB & Certificates WG~~
- ~~• 14/03/2019 – UDI & Device WG~~
- 21/03/2019 - Data Exchange WG
- 28/03/2019 – Vigilance WG
- 16/05/2019 – Clinical Investigations WG
- 23/05/2019 – Market Surveillance WG
- 20/06/2019 – Certificates WG

Working documents: done

- Data modelling - XSDs + description of the models
 - Actors
 - Actor registration
 - UDID
 - CRF (on-going)
- Service definitions:
 - Actors
 - Actor registration
 - UDID registration & updates
 - CRF
- Architecture overview
- Basic implementation for Actors downloads

Implementation plan overview for 1st release

| | Analysis done (%) |
|---|-------------------|
| FS-ACT-004 : Machine to machine (M2M) Actors data Download – for CA only | 100 |
| FS-ACT-008.01 : Enable a CA to download in a file submitted actor registration requests this CA has to validate | 100 |
| FS-ACT-008.02 : Enable a CA to upload from a file validation outcomes for submitted actor registration requests this CA has to validate | 100 |
| FS-UDID-008.01: Enable manufacturers to submit through upload (M2M or XML file) the required information on Basic UDI-DI, UDI-DI and device data | 95 |
| FS-UDID-008.02: Enable System/Procedure pack Producer to submit through upload (M2M or XML file) the required information on Basic UDI-DI and UDI-DI | 95 |
| FS-UDID-008.03: Enable downloading (M2M) the registered (Basic) UDI-DI data and Device data or to extract in an electronic format a search result list | 95 |
| FS-CRF-019.01: Import using a M2M web service certificates NB own information from their database to Eudamed for submission certificates | 70 |
| FS-CRF-020.02: Export using a M2M web service information submitted for a conformity assessment or a certificate by NB | 70 |
| FS-VGL-008.04: Enable the MF/AR to upload (M2M or with XML file) an initial, follow up (updates), combined initial and final and/or a final serious incident report | 0 |
| FS-VGL-008.05: Enable the MF/AR to upload (M2M or with XML file) an initial, follow up (updates) and/or a final FSCA report | 0 |
| FS-VGL-008.06: Enable the MF/AR to upload (M2M) proposed draft FSN for comments by CA or final FSN for public access | 0 |
| FS-VGL-009.06: Enable downloading (M2M) of an initial, follow up (updates), combined initial and final and/or a final serious incident report submitted by a MF/AR | 0 |
| FS-VGL-009.07: Enable downloading (M2M) of an initial, follow up (updates), and/or a final FSCA report submitted by a MF/AR implemented/to be implemented | 0 |
| FS-VGL-009.08: Enable downloading (M2M) of a draft or final FSN submitted by a MF/AR together with existing comments coming from other CA(s) | 0 |
| FS-VGL-009.12: Enable downloading (M2M) the outcome of the assessment from other CA(s) for incidents and FSCAs | 0 |

State of play 1st release: ACT

- FS-ACT-004 : Machine to machine (M2M) **Actors data Download – for CA only**
 - Analysis completed
- FS-ACT-008.01 : **Enable a CA to download in a file submitted actor registration requests** this CA has to validate
 - Analysis completed
- FS-ACT-008.02 : **Enable CA to upload from a file validation outcomes** for submitted actor registration requests this CA has to validate
 - Analysis completed

State of play 1st release: UDI

- FS-UDID-008.01: Enable **manufacturers** to **submit through upload** (M2M or XML file) **the required information** (new and update) **on Basic UDI-DI, UDI-DI and device data** (with bulk upload providing multiple records possibility)
 - Analysis on-going (95%)
- FS-UDID-008.02: Enable **System/Procedure pack Producer** to **submit** through upload (M2M or XML file) **the required information on** (new and update) **on Basic UDI-DI and UDI-DI**
 - Analysis on-going (95%)
- FS-UDID-008.03: Enable **downloading** (M2M) the **registered (Basic) UDI-DI data and Device data** or to extract in an electronic format a search result list - (SSCP included)
 - Analysis on-going (95%)

State of play 1st release: CRF

- FS-CRF-019.01: **Import** using a M2M web service **certificates NB own information** from their database to Eudamed for submission of issued, updates, renewal and refused certificates (upload from NB to Eudamed)
 - Analysis on-going (70%)
- FS-CRF-020.02: **Export** using a M2M web service **information submitted for a conformity assessment or a certificate** by NB together with related information in Eudamed to the national MS database of that CA - only CA/DA
 - Analysis on-going (70%)

State of play 1st release: VGL 1/2

- FS-VGL-008.04: Enable the **MF/AR to upload** (M2M or with XML file) an initial, follow up (updates), combined initial and final and/or a final **serious incident report**
 - Analysis to be started
- FS-VGL-008.05: Enable the **MF/AR to upload** (M2M or with XML file) an initial, follow up (updates) and/or a final **FSCA report**
 - Analysis to be started
- FS-VGL-008.06: Enable the **MF/AR to upload** (M2M) **proposed draft FSN for comments by CA or final FSN for public access**
 - Analysis to be started
- FS-VGL-009.06: Enable **downloading** (M2M) of an initial, follow up (updates), combined initial and final and/or a final **serious incident report** submitted by a MF/AR
 - Analysis to be started

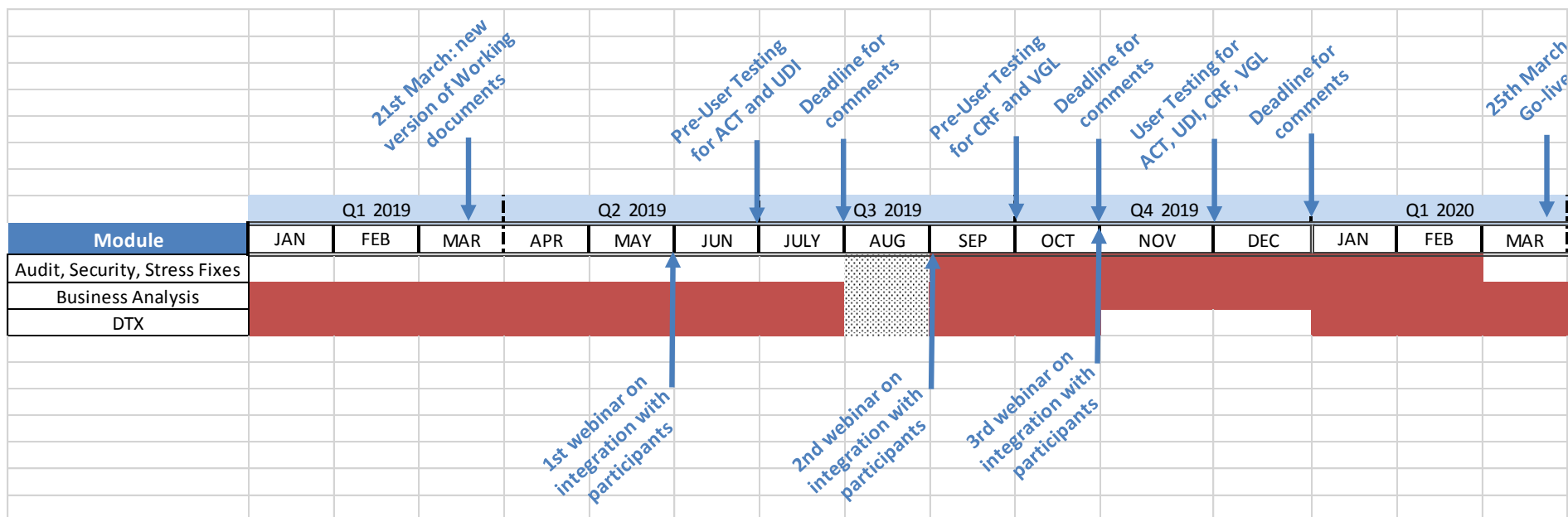
State of play 1st release: VGL 2/2

- FS-VGL-009.07: Enable **downloading** (M2M) of an initial, follow up (updates), and/or a final **FSCA report** submitted by a MF/AR implemented/to be implemented
 - Analysis to be started
- FS-VGL-009.08: Enable **downloading** (M2M) of a **draft or final FSN** submitted by a MF/AR together with existing comments coming from other CA(s)
 - Analysis to be started
- FS-VGL-009.12: Enable **downloading** (M2M) the **outcome of the assessment** from other CA(s) **for incidents and FSCAs**
 - Analysis to be started

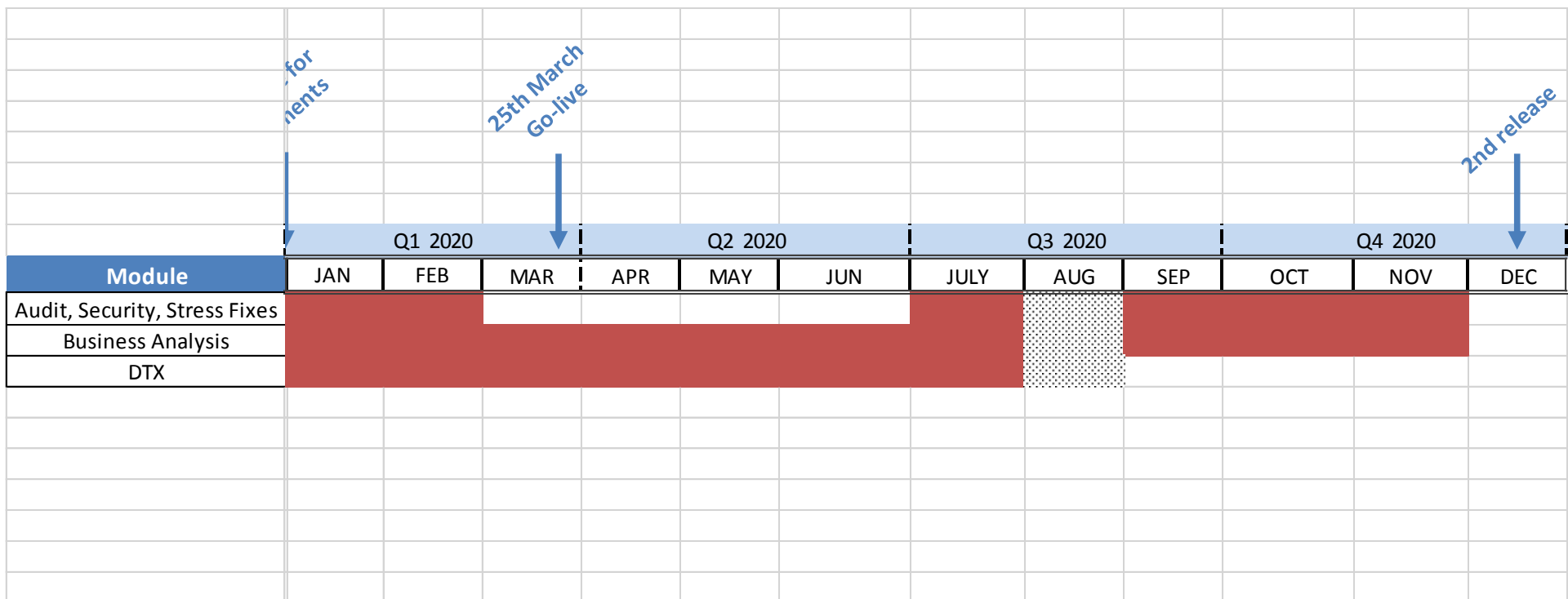
Introduction webinars

- **Purpose:** introduction to the integration with Data Exchange for Information Systems that will connect to Eudamed
- **Target organisations:** Economical Operators, Competent Authorities, Notified Bodies, Third Party Providers
- **Target public:** IT specialists
- **Duration:** 4h
- **Dates:** this will be communicated in due time. Draft planning presented in the Implementation Plan.
- **How to connect:** through webinar connection. A PC with Internet connection is required. Instructions will be provided in due time.

Implementation plan update 2019



Implementation plan update 2020



Next WG meeting

- **Date:** not before September 2019 (date will be communicated in due time)

Thanks for your attention

- Questions?